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|------------------------|-----------------------|-----------------------|----------------------------|
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| David K.S. Cornwell    | Crystal D. Sayles     | Bruce E. Chalker      | Hélène C. Carlson          |
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| Eric K. Steffe         | Teresa U. Medler      | Lawrence J. Carroll*  | Mark B. Tung               |
| Michael Q. Lee         | Jeffrey S. Weaver     | George S. Bardmesser  | Katrina Y. Pei             |
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May 20, 2002

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Commissioner for Patents  
Washington, D.C. 20231

MAY 21 2002

Art Unit 1632

TECH CENTER 1600/2900

Re: U.S. Continuation Utility Patent Application  
Appl. No. 10/024,597; Filed: December 21, 2001  
For: **Fusion Proteins Incorporating Lysozyme**  
Inventors: Cottingham *et al.*  
Our Ref: 0623.0730002/LBB/BJD

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement;
2. 12 pages of Form PTO-1449 citing 57 documents;
3. A copy of each of the 57 cited documents; and
4. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents  
May 20, 2002  
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency,  
or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Brian J. Del Buono  
Attorney for Applicants  
Registration No. 42,473

BJD/nef  
Enclosures

SKGF\_DC1:15267.1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Cottingham *et al.*

Appl. No. 10/024,597

Filed: December 21, 2001

For: **Fusion Proteins Incorporating  
Lysozyme**

Confirmation No. 2450

Art Unit: 1632

Examiner: *To Be Assigned*

Atty. Docket: 0623.0730002/LBB/BJD

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MAY 21 2002  
TECH CENTER 1600/2900

### Information Disclosure Statement

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. A copy of each document is provided.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following concise statement regarding the relevance of the non-English language documents AP1, AN2 and AR1 cited on Form PTO 1449:

Document AP1, WIPO Publication No. WO 92/22644 A1, is in the French language. An unverified English language summary thereof appears on the face page of the publication.

Document AN2, European Patent Office Publication No. 0 590 530, in the name of Behringwerke Aktiengesellschaft, is in the German language. An unverified English language abstract of this publication (from Derwent WPI) is included herewith as Document AT12.

Document AR1, Brignon and Ribadeau-Dumas, *Biochimie* 64:231-235 (1982), is in the French language. An unverified English language summary thereof appears on page 231 of the publication.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

Cottingham *et al.*  
Appl. No. 10/024,597

The U.S. Patent and Trademark Office is hereby authorized to charge any fee  
deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Brian J. Del Buono  
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Date: May 20, 2002

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|--|--|--|-------------------------------|
| FORM PTO-1449<br><br><b>INFORMATION DISCLOSURE STATEMENT</b> |  | ATTY. DOCKET NO.<br>0623.0730002/EKS/BJD | APPLICATION NO.<br>10/024,597 |
|  |  | APPLICANT<br>Cottingham et al.           |                               |
|  |  | FILING DATE<br>December 21, 2001         | GROUP<br>1632                 |

**U.S. PATENT DOCUMENTS**

| EXAMINER INITIAL |     | DOCUMENT NUMBER | DATE       | NAME               | CLASS | SUB-CLASS | FILING DATE |
|------------------|-----|-----------------|------------|--------------------|-------|-----------|-------------|
|                  | AA1 | 5,322,775       | 06/21/1994 | Clark et al.       | 435   | 69.1      | 11/22/1991  |
|                  | AB1 | 5,366,894       | 11/22/1994 | Clark et al.       | 435   | 320.1     | 11/22/1991  |
|                  | AC1 | 5,476,995       | 12/19/1995 | Clark et al.       | 800   | 2         | 08/18/1992  |
|                  | AD1 | 5,610,053       | 03/11/1997 | Chung et al.       | 435   | 172.3     | 07/29/1994  |
|                  | AE1 | 5,620,923       | 04/15/1997 | Rechsteiner et al. | 435   | 69.7      | 04/03/1992  |
|                  | AF1 | 5,650,503       | 07/22/1997 | Archibald et al.   | 536   | 23.5      | 12/20/1994  |
|                  | AG1 | 5,827,690       | 10/27/1998 | Meade et al.       | 435   | 69.6      | 12/20/1993  |
|                  | AH1 | 5,861,299       | 01/19/1999 | Archibald et al.   | 435   | 240.2     | 11/17/1994  |
|                  | AII | 6,211,427 B1    | 04/03/2001 | Cottingham et al.  | 800   | 7         | 10/08/1996  |
|                  | AJ  |                 |            |                    |       |           |             |
|                  | AK  |                 |            |                    |       |           |             |

**FOREIGN PATENT DOCUMENTS**

| EXAMINER INITIAL |     | DOCUMENT NUMBER | DATE       | COUNTRY | CLASS | SUB-CLASS | TRANSLATION    |
|------------------|-----|-----------------|------------|---------|-------|-----------|----------------|
|                  | AL1 | EP 0 181 634 A2 | 05/21/1986 | Europe  |       |           | Yes<br>No      |
|                  | AM1 | WO 88/00239 A1  | 01/14/1988 | WIPO    |       |           | Yes<br>No      |
|                  | AN1 | WO 90/05188 A1  | 05/17/1990 | WIPO    |       |           | Yes<br>No      |
|                  | AO1 | WO 92/11358 A1  | 07/09/1992 | WIPO    |       |           | Yes<br>No      |
|                  | AP1 | WO 92/22644 A1  | 12/23/1992 | WIPO    |       |           | X<br>Yes<br>No |

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

|  |    |   |   |
|--|----|---|---|
|  | AR | 1 | Brignon, G. and Ribadeau-Dumas, B., "A new method for human milk protein separation," <i>Biochimie</i> 64:231-235, Masson (1982).   |
|  | AS | 1 | Clark, A.J., et al., "Rescuing Transgene Expression By Co-Integration," <i>Bio/Technol.</i> 10:1450-1454, Nature Publishing Co. (1992).   |
|  | AT | 1 | Curtis, R.A., et al., "Protein-Protein and Protein-Salt Interactions in Aqueous Protein Solutions Containing Concentrated Electrolytes," <i>Biotechnol. Bioeng.</i> 57:11-21, John Wiley & Sons, Inc. (January 1998). |

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|---|-----------------|
| EXAMINER  | DATE CONSIDERED |
| <b>EXAMINER:</b> Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant. |                 |



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## FOREIGN PATENT DOCUMENTS

| EXAMINER INITIAL |     | DOCUMENT NUMBER | DATE       | COUNTRY | CLASS | SUB-CLASS | TRANSLATION |
|------------------|-----|-----------------|------------|---------|-------|-----------|-------------|
|                  | AL2 | WO 93/25567 A1  | 12/23/1993 | WIPO    |       |           | Yes No      |
|                  | AM2 | WO 94/04672 A1  | 03/03/1994 | WIPO    |       |           | Yes No      |
|                  | AN2 | EP 0 590 530 A2 | 04/06/1994 | Europe  |       |           | X Yes No    |
|                  | AO2 | WO 95/27782 A1  | 10/19/1995 | WIPO    |       |           | Yes No      |
|                  | AP2 | EP 0 771 874 A2 | 05/07/1997 | Europe  |       |           | Yes No      |

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

|  |    |   |   |
|--|----|---|---|
|  | AR | 2 | During, K. "A Tightly Regulated System for Overproduction of Bacteriophage T4 Lysozyme in <i>Escherichia coli</i> ," <i>Protein. Expr. Purif.</i> 4:412-416, Academic Press, Inc. (1993).                               |
|  | AS | 2 | Eipper, B.A., et al., "The Biosynthesis of Neuropeptides: Peptide $\alpha$ -Amidation," <i>Annu. Rev. Neurosci.</i> 15:57-85, Annual Reviews Inc. (1992).   |
|  | AT | 2 | Eipper, B.A., et al., "Peptidylglycine $\alpha$ -amidating monooxygenase: A multifunctional protein with catalytic, processing, and routing domains," <i>Protein Sci.</i> 2:489-497, Cambridge University Press (1993). |

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| FORM PTO-1449<br><br><u>INFORMATION DISCLOSURE STATEMENT</u> |  | ATTY. DOCKET NO.<br>0623.0730002/EKS/BJD | APPLICATION NO.<br>10/024,597 |
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|------------------|----|-----------------|------|------|-------|-----------|-------------|
|                  | AA |                 |      |      |       |           |             |
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## FOREIGN PATENT DOCUMENTS

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|------------------|-----|-----------------|------------|---------|-------|-----------|-------------|
|                  | AL3 | WO 97/42835 A1  | 11/20/1997 | WIPO    |       |           | Yes<br>No   |
|                  | AM3 | WO 00/29588 A1  | 05/25/2000 | WIPO    |       |           | Yes<br>No   |
|                  | AN  |                 |            |         |       |           | Yes<br>No   |
|                  | AO  |                 |            |         |       |           | Yes<br>No   |
|                  | AP  |                 |            |         |       |           | Yes<br>No   |

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

|    |   |  |
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| AR | 3 | Fischer, B., et al., "Physiological consequence of expression of soluble and active hen egg white lysozyme in <i>Escherichia coli</i> ," <i>Appl. Microbiol. Biotechnol.</i> 39:537-540, Springer-Verlag (1993). |
| AS | 3 | Goldman, A.S., et al., "Immunologic factors in human milk during the first year of lactation," <i>J. Pediatr.</i> 100:563-567, C.V. Mosby Co. (1982).  |
| AT | 3 | Han, K.-K., et al., "Current Developments in Chemical Cleavage of Proteins," <i>Int. J. Biochem.</i> 15:875-884, Pergamon Press Ltd. (1983).   |

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| EXAMINER INITIAL                |    | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB-CLASS | TRANSLATION |
|                                 | AL |                 |      |         |       |           | Yes<br>No   |
|                                 | AM |                 |      |         |       |           | Yes<br>No   |
|                                 | AN |                 |      |         |       |           | Yes<br>No   |
|                                 | AO |                 |      |         |       |           | Yes<br>No   |
|                                 | AP |                 |      |         |       |           | Yes<br>No   |

| <b>OTHER (Including Author, Title, Date, Pertinent Pages, etc.)</b> |    |   |   |  |  |  |  |
|---|----|---|---|--|--|--|--|
|   | AR | 4 | Houdebine, L.-M., "Production of pharmaceutical proteins from transgenic animals," <i>J. Biotechnol.</i> 34:269-287, Elsevier Science B.V. (1994).  |  |  |  |  |
|   | AS | 4 | Ibrahimi, I.M., et al., "Determinants for protein translocation across mammalian endoplasmic reticulum. Membrane insertion of truncated and full-length prelysozyme molecules," <i>Eur. J. Biochem.</i> 155:571-576, Springer International (1986). |  |  |  |  |
|   | AT | 4 | Jacquot, J., et al., "Identification of Different Molecular Forms of Human Airway Lysozyme," <i>Anal. Biochem.</i> 160:227-232, Academic Press, Inc. (1987).  |  |  |  |  |

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| FOREIGN PATENT DOCUMENTS |    |                 |      |         |       |           |             |
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| EXAMINER INITIAL         |    | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB-CLASS | TRANSLATION |
|                          | AL |                 |      |         |       |           | Yes<br>No   |
|                          | AM |                 |      |         |       |           | Yes<br>No   |
|                          | AN |                 |      |         |       |           | Yes<br>No   |
|                          | AO |                 |      |         |       |           | Yes<br>No   |
|                          | AP |                 |      |         |       |           | Yes<br>No   |

| OTHER (Including Author, Title, Date, Pertinent Pages, etc.) |          |        |  |  |  |  |  |
|--|----------|--------|--|--|--|--|--|
|  | EXAMINER | REF ID |  |  |  |  |  |
|  | AR       | 5      |  | Jespers, L., et al., "Overexpression of the phage lambda lysozyme cloned in <i>Escherichia coli</i> : use of a degenerative mixture of synthetic ribosome binding sites and increase of the protein stability <i>in vivo</i> ," <i>Protein Eng.</i> 4:485-492, Oxford University Press (1991). |  |  |  |
|  | AS       | 5      |  | Lee, S.H. and de Boer, H.A., "Production of biomedical proteins in the milk of transgenic dairy cows: the state of the art," <i>J. Control. Rel.</i> 29:213-221, Elsevier Science B.V. (1994).   |  |  |  |
|  | AT       | 5      |  | Lindahl, L., and Vogel, H.J., "Metal-Ion-Dependent Hydrophobic-Interaction Chromatography of $\alpha$ -Lactalbumins," <i>Anal. Biochem.</i> 140:394-402, Academic Press, Inc. (1984).  |  |  |  |

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|                                 | AO |                 |      |         |       |           | Yes<br>No   |
|                                 | AP |                 |      |         |       |           | Yes<br>No   |

| <b>OTHER (Including Author, Title, Date, Pertinent Pages, etc.)</b> |    |   |  |  |  |  |  |
|---|----|---|--|--|--|--|--|
|   | AR | 6 | Lollike, K., et al., "Purification of Lysozyme from Human Neutrophils, and Development of an ELISA for Quantification in Cells and Plasma," Leukemia 9:206-209, Stockton Press (1995).   |  |  |  |  |
|   | AS | 6 | Lönnnerdal, B., et al., "A longitudinal study of the protein, nitrogen, and lactose contents of human milk from Swedish well-nourished mothers," Am. J. Clin. Nutr. 29:1127-1133, American Society of Clinical Nutrition (1976). |  |  |  |  |
|   | AT | 6 | McCreath, G.E., et al., "Preparation and use of ion-exchange chromatographic supports based on perfluoropolymers," J. Chrom. A. 773:73-83, Elsevier Science B.V. (1997).   |  |  |  |  |

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|  |  | APPLICANT<br>Cottingham et al.           | FILING DATE<br>December 21, 2001 |
|  |  | GROUP<br>1632                            |                                  |

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|                          | AM |                 |      |         |       |           | Yes<br>No   |
|                          | AN |                 |      |         |       |           | Yes<br>No   |
|                          | AO |                 |      |         |       |           | Yes<br>No   |
|                          | AP |                 |      |         |       |           | Yes<br>No   |

| OTHER (Including Author, Title, Date, Pertinent Pages, etc.) |    |   |  |   |  |  |  |
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|                          | AL |                 |      |         |       |           | Yes<br>No   |
|                          | AM |                 |      |         |       |           | Yes<br>No   |
|                          | AN |                 |      |         |       |           | Yes<br>No   |
|                          | AO |                 |      |         |       |           | Yes<br>No   |
|                          | AP |                 |      |         |       |           | Yes<br>No   |

| OTHER (Including Author, Title, Date, Pertinent Pages, etc.) |    |   |   |  |  |  |  |
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|                          | AN |                 |      |         |       |           | Yes<br>No   |
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|                          | AP |                 |      |         |       |           | Yes<br>No   |

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|  | EXAMINER INITIAL | REF ID         | NUMBER | DESCRIPTION  |  |  |  |
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|  | AS               | <u>12</u><br>— |        | NCBI Entrez, Genbank Accession No. X14008, from Sippel, A.E., National Center for Biotechnology Information (1997).  |  |  |  |
|  | AT               | <u>12</u>      |        | Unverified English language abstract of EP 0 590 530 A2 (Document AN2), Derwent World Patent Index (Dialog File 351), Derwent WPI Acc. No. 94-111012/14, Derwent Info Ltd. (1997). |  |  |  |

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